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K022635

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Kuske Breast Applicator Set
Common/Usual Name:	Remote Controlled Afterloading System
Classification Name:	Radiotherapy Device
Classification:	Class II

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	K953946 microSelectron-HDR V2	K953946

Description:

The purpose of the Modification of the Device is to is to provide a tool for guiding the needles on a well determined position through the breast. The Kuske Breast Applicator Set is based on the microSelectron HDR V2 Breast Template for interstitial breast treatment. The template has been slightly modified in shape and hole alignment to accommodate dimensions of the breast.

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The main shape of the Kuske Breast Applicator is a bridge supporting 2 templates which will be positioned at both sides of the breast. Each template contains well dimensioned holes which guide the needles in a straight way through the breast. Coordinates for each hole provide position information. The needles are exchanged after placing the flexible implant catheters, which will be connected to the afterloader.

The material for the Kuske Breast Applicator has been changed, to accommendate the use of CT/MR techniques. The Kuske Breast Applicator Set uses similar materials as the legally marketed predicate device cited (MicroSelectron HDR V2: CT/MR Ring Applicator). With respect to the the legally marketed predicate device cited (MicroSelectron HDR V2: Breast Template), the shape has been changed and the number of holes has been increased to accommendate better needle placement.

The Kuske Breast Applicator Set is an accessory to the microSelectron-HDR (V2).

Intended use:

The Nucletron Kuske Breast Applicator Set has the same intended use as the legally marketed predicate device cited:

Nucletron Kuske Breast Applicator Set is intended for use with Interstitial breast brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR, mHDR-Classic, mPDR and mLDR.

The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

Summary of technological considerations:

The Kuske Breast Applicator Set is substantially equivalent to the cleared predicate device, microSelectron-HDR V2, 510(k)#: K953946.

H. Schot

22-7-2002

Name: H. Schot
Title: i.a. Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K022635
Trade/Device Name: Kuske Breast Applicator Set
Model 189.006
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide
applicator set
Regulatory Class: II
Product Code: 90 JAQ
Dated: August 6, 2002
Received: August 8, 2002

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022635

Device Name: Kuske Breast Applicator Set Model 189.006

Indications For Use:

The Kuske Breast Applicator Set has the same intended use as the legally marketed predicate device cited:

Nucletron Kuske Breast Applicator Set is intended for use with Interstitial breast brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR, mHDR-Classic, mPDR and mLDR.

The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Jegmm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022635

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)